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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,607	11/08/2001	Richard T. Lee	B0801.70231US00	6830

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EXAMINER

HISSONG, BRUCE D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,607	LEE, RICHARD T.	
	Examiner	Art Unit	
	Bruce D. Hisson	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/1/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-2,6-8 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-8 and 10 is/are rejected.
- 7) ☒ Claim(s) 1 and 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION***A. Formal Matters***

Applicant's election of Group II and the gene Fit-1, in the reply filed on 07/30/2005 is acknowledged. In the amendment filed on 11/08/2001, Applicant cancelled claims 3-5, 9, and 11-12. Therefore, Group II claims 8 and 10, as well as linking claims 1-2 and 6-7 are currently pending and are the subject of this Office Action.

B. Claim Objections

Claim 1 is objected to for having improper syntax. Due to the election of Fit-1, the language of the claim can be improved by amending the claim to read on "expression of Fit-1 or an expression product thereof".

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, claim 2 depends from claim 1, which reads on a method of diagnosing cardiovascular disease by measuring expression of Fit-1. Due to the election of Fit-1, claim 2 only reads on a method of diagnosing cardiovascular disease by measuring expression of Fit-1, and as such, does not further limit the subject matter of claim 1.

C. Claim Rejections - 35 USC § 112, 1st paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 6-8, and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The factors to be considered when determining if the disclosure satisfies the enablement requirement have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of

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the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breath of claims. *Ex Parte Forman*, (230 USPQ 546 (Bd. Pat. App. & Int. 1986); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

1. Claims 1-2, 6-8, and 10 are drawn to methods of diagnosing cardiovascular conditions by determining aberrant expression of "a fragment of an expression product thereof". While the specification is enabling for the use of full-length Fit-1 as a diagnostic marker of cardiovascular conditions, the specification is not enabling for fragments of Fit-1. The specification does not provide any working examples of aberrant expression of naturally occurring fragments of Fit-1 that are associated with cardiovascular disease, and provides no guidance on how such fragments could be correlated with disease. A person of ordinary skill in the art would therefore not know how to use fragments of Fit-1 in methods of diagnosing cardiovascular disease. Furthermore, the specification does not teach how to make reagents that would specifically differentiate the many possible Fit-1 fragments. For these reasons, which include the complexity and unpredictability of the art and the invention, a skilled artisan would not know how to use Fit-1 fragments to diagnose cardiovascular disorders, and determination of how to use Fit-1 fragments would require undue experimentation by the skilled artisan.

2. Claims 8 and 10 are drawn to methods of diagnosing cardiovascular conditions by monitoring "an antibody which selectively binds the polypeptide or peptide" and "a polypeptide or peptide which binds the antibody of (iv)." The specification does not provide any examples of naturally occurring anti-Fit-1 antibodies, or antibodies against Fit-1 peptides, that are present in a patient with a cardiovascular disorder, and are thus indicative of disease. Furthermore, the specification does not teach the identities of any polypeptides or peptides, other than those of SEQ ID NO: 1 and 3, which would be capable of binding to an anti-Fit-1 antibody. There are no examples in the specification that would teach a skilled artisan how to make these polypeptides or peptides, or how to use them commensurate with the scope of the claims. Due to the lack of working examples and guidance in the specification, it would therefore require undue experimentation on the part of a person of ordinary skill in the art to know how to use the claimed invention.

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3. Claims 1-2, 6-8, and 10 are drawn to methods of assessing “aberrant” expression of Fit-1 nucleic acid, polypeptides, peptides, or antibodies. The specification, on page 29, lines 11-15, defines *decreased* expression of Fit-1 as indicative of the presence of cardiovascular disease, or of the risk for developing cardiovascular disease. However, there are no working examples in the specification that would suggest that decreased expression of Fit-1 correlates with cardiovascular disease. The examples do show an *increased* expression of Fit-1 in cardiovascular tissue in response to mechanical stress. Additionally, there are no examples in the specification that teach that the cardiovascular diseases of claims 6-7 are associated with aberrant Fit-1 expression. The specification does not teach how to differentiate among the diseases of claims 6-7 simply by means of determining Fit-1 expression. Similarly, claim 8 reads on determining the stage of cardiovascular disease; however, the specification does not provide guidance or working examples of Fit-1 levels identified for any stages of a cardiovascular disease. A person of ordinary skill in the art would not be able to predict what levels of Fit-1 expression would be indicative of specific stages of disease. Therefore, while the specification is enabling for increased Fit-1 expression, the specification is not enabling for decreased Fit-1 expression as indicative of cardiovascular disease, or of specific stages of cardiovascular disease. Because of the complexity and unpredictability of the invention, and the lack of working examples that show that decreased Fit-1 expression correlates with cardiovascular disease, a person of ordinary skill in the art would require undue experimentation in order to use the invention commensurate with the scope of the claims.

4. Claims 1-2, 6-8, and 10 are drawn to methods of diagnosing cardiovascular disease using Fit-1 nucleic acids, polypeptides, or peptides. The specification, while being enabling for the nucleic acids and polypeptides of SEQ ID NO:1-4, is not enabling for any other nucleic acid or polypeptide sequences. A person of ordinary skill in the art would know that other nucleic acids and polypeptides would have additions, subtractions, deletions, and/or substitutions when compared to the nucleic acids and polypeptides of SEQ ID NO:1-4. The Applicant has not taught what residues of Fit-1 must be retained to maintain the function of Fit-1 molecules other than those of SEQ ID NO:1-4, nor is it predictable which residues to change. The claims also read on peptides that are “derived from” the sequences of SEQ ID NO:1-4. The Applicant has not taught which residues can be changed, and which residues must be preserved in order to maintain a “signature” sequence. The specification suggests that one of ordinary skill in the art

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would be able to determine this using the sequences of SEQ ID NO:1-4 and commonly available software/algorithms. This would constitute under experimentation on the part of the skilled artisan. The artisan would not know which residues must be maintained in order to use the peptides in the manner claimed because the Applicant has not taught that Fit-1 nucleic acids, polypeptides, or peptides derived from Fit-1, other than the sequences of SEQ ID NO:1-4, can be used in the present methods. Because of the breadth of the claims, which encompass nucleic acids, polypeptides, and peptides other than SEQ ID NO:1-4, the lack of guidance and examples showing how to make or use these molecules, and the unpredictability of the invention, a skilled artisan would not know how to make or use the invention as claimed.

5. Claim 10 is drawn to a method of determining the stage of cardiovascular disease by contacting a sample with a detectable agent, such as "(a) an isolated nucleic acid molecule which selectively hybridizes.....". The specification does not teach the identities of any nucleic acids other than those of SEQ ID NO: 1 and 3, and the applicant has not taught how to make a probe/primer that selectively hybridizes to nucleic acids other than those of SEQ ID NO:1 and 3. A person of ordinary skill in the art would therefore not know how to make, and subsequently use, any nucleic acids that would be capable of selectively hybridizing to nucleic acids other than those of SEQ ID NO:1 and 3.

6. Claims 1-2, 6-8, and 10 are drawn to methods of determining Fit-1 expression in a "biological sample." The specification teaches that a biological sample can include tissues such as blood, or cardiac tissue obtained, for example, via biopsy. The examples provided in the specification teach that Fit-1 mRNA is expressed in cardiac myocytes, and also in Th2 lymphocytes, but does not disclose expression in other cell types commonly found in blood, such as myeloid cells, or in the serum and plasma components of blood. A person of ordinary skill in the art would not know how to use the invention as claimed, because the specification does not provide guidance or examples for detection of Fit-1 nucleotides or polypeptides in these tissues. Therefore, the specification, while enabling for detection of Fit-1 mRNA in cardiac tissue and Th2 lymphocytes, is not enabling for detection of Fit-1 mRNA or protein, as a diagnostic measure of cardiovascular disease, in any other cell- or tissue-type. Furthermore, T1/ST2/Fit-1 has been shown by others to be inducible in monocytes in response to LPS stimulation (Saccani *et al*, *Cytokine*, 1998, 10(10):773-780). The specification does not teach

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methods to discriminate Fit-1 expression associated with cardiovascular disease from Fit-1 induced by the presence of LPS, which could occur in patients infected with gram negative bacteria. It would require undue experimentation of the part of a skilled artisan to determine the expression of Fit-1 in lymphoid/myeloid cells as it relates to cardiovascular disease, and to discriminate between Fit-1 expression associated with cardiovascular disease from that associated with other conditions. For these reasons, and taking into account the unpredictability of the invention and the breath of the claims, which read on samples encompassing both cardiac and blood tissues, a person of ordinary skill in the art would not know how to use the claimed invention.

D. Claim Rejections - 35 USC § 112, first paragraph – written description

Claims 1-2, 6-8, and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

1. Claims 1-2, 8, and 10, are drawn to methods of diagnosing cardiovascular conditions by determining aberrant expression of Fit-1 nucleic acids or polypeptides. The specification discloses the rat and mouse nucleotide and polypeptide sequences for Fit-1S and Fit-1M; however the preferred embodiments of the invention include human Fit-1 nucleic acid, polypeptides, and related peptides. The applicant is therefore claiming a genus of nucleic acids and peptides that are not supported in the specification. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient identifying characteristics of the genus, such as the sequence similarity to the disclosed rat Fit-1 nucleic acids and polypeptides. Because the specification fails to teach any identifying characteristics of the genus encompassing human Fit-1 nucleic acids and polypeptides, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

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possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polypeptides comprising the amino acid sequence set forth in SEQ ID NO:2 and 4, or encoded by SEQ ID NO:1 and 3, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

2. Claim 10 is drawn to peptides that bind to the antibody of (iv – claim 8), and an antibody that selectively binds the peptide of (iii – claim 8). The specification does not disclose any distinguishing characteristics of peptides related to Fit-1 peptides, other than they must be a "signature" for the larger Fit-1 polypeptide. The Applicant is therefore claiming a genus of peptides whose only common feature is homology to the mature Fit-1 polypeptide. In the absence of any further structural/sequence characteristics, biochemical properties, structure/function correlation, methods of making the claimed product, or any combination thereof, the specification does not provide adequate written description of the claimed genus. Additionally, claim 10(c) reads on "a polypeptide or peptide that binds the antibody of (iv)". However, because the specification does not disclose any polypeptides or peptides, other than those of SEQ ID NO:1 and 3, the Applicant is claiming a genus that does have adequate written

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description, and there is no evidence that Applicant was in possession of the claimed genus at the time of the invention.

3. Claims 1-2, 6-8, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims read on methods of assessing "aberrant" expression of Fit-1 nucleic acids, polypeptides, peptides, or antibodies. In the instant case, the omitted steps are: a specific recitation of what controls will be used to determine if Fit-1 expression is "aberrant."

4. Claim 10 is drawn to a method of diagnosing cardiovascular disease using Fit-1 nucleic acids, polypeptides, and peptides. Applicant is claiming a genus of nucleic acids, polypeptides, and peptides that are not supported by the specification, since the specification does not teach the identities of any other nucleic acids or polypeptides other than those of SEQ ID NO:1-4. The specification does not teach any identifying characteristics of nucleic acids or polypeptides other than those of SEQ ID NO:1-4, and therefore the specification does not provide adequate written description of the claimed genus, or evidence of possession at the time of invention.

The claims are also drawn to methods of determining the stage of cardiovascular disease by contacting a sample with a detectable agent, such as "(a) an isolated nucleic acid molecule which selectively hybridizes.....". Applicant is claiming a genus of nucleic acids that is not supported by the specification, since the specification does not teach the identities of any nucleic acids that are capable of hybridizing to nucleic acids other than those of SEQ ID NO: 1 and 3. Because the specification fails to teach any identifying characteristics of the genus encompassing nucleic acids and capable of hybridizing to the claimed sequences, the specification does not provide adequate written description of the claimed genus, or evidence of possession of the claimed genus at the time of the invention.

E. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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1. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim reads on "(ii) a polypeptide encoded by the nucleic acid", and is indefinite because it fails to state which nucleic acid encodes the polypeptide. The Examiner suggests that the claim be amended to read "a polypeptide encoded by the nucleic acid of part (i).

2. Claim 10 is vague and indefinite since the claim recites "stringent conditions." It is not known what these conditions are. Nucleic acid molecules that hybridize under conditions of "low" stringency would not necessarily hybridize under conditions of "high" stringency. Furthermore, not all conditions of "high" or "low" stringency, for example, are the same. Therefore, it is required that Applicants amend the claims to recite the exact hybridization conditions without using indefinite phrases, such as "*for example*", **without adding new matter**.

F. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 6-8, and 10, are rejected under 35 U.S.C. 103 as being unpatentable over Kumar *et al* (*Biochem Biophys Res Commun*, 1997, 235(3):474-8), in view of Baumgarten *et al* (*Trends Cardiovasc Med*, 2000, 10(5):216-223). The claims of the instant application are drawn to methods of diagnosing cardiovascular disease, with aberrant expression of Fit-1 as being indicative of the presence of disease. Kumar *et al* shows that expression of ST2 (the mouse homolog of Fit-1) mRNA and protein is induced by pro-inflammatory stimuli, including the cytokines TNF and IL-1 α/β . Baumgarten *et al* describe numerous examples of cardiovascular disease associated with elevated levels of cytokines, including TNF and IL-1 (see Table II, p

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217). Given the correlation between cardiovascular disease and increased TNF and IL-1 expression reviewed in Baumgartner *et al*, it would have been obvious for a skilled artisan, at the time of the instant invention, to incorporate the teaching of Baumgarten *et al* to use common cytokine-inducible genes, or their encoded polypeptides, in methods of diagnosing cardiovascular disease, including those recited in claims 6-7. In demonstrating that Fit-1 expression is induced by the pro-inflammatory cytokines TNF and IL-1, whose levels, as described above, are elevated in patients with cardiovascular disease, Kumar *et al* provide motivation for one of ordinary skill in the art to use Fit-1/ST2 as a marker for cardiovascular disease. By combining the teachings of Kumar *et al* with those of Baumgarten *et al*, a skilled artisan would have a reasonable expectation of success in achieving the claimed invention of the instant application.

G. Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6-8, and 10 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-3, 7, and 9 of copending Application No. 10/435482 (US 2004/0048286 A1 – pre-grant pub). This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

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The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The claimed inventions of both applications encompass methods using aberrant expression of Fit-1/T1/ST2 nucleotides, polypeptides, and derived-peptides in the diagnosis of cardiovascular disorders. Application No. 10/435482 claims the use of nucleotides and polypeptides of human T1/ST2 in the diagnosis of cardiovascular disease, while the instant application, and the subject of this Office Action, discloses rat and murine Fit-1 nucleotide and polypeptide sequences. However, the Applicants state in the specification of the instant application that the preferred embodiments of the invention of the instant application utilize human T1/ST2/Fit-1 in the diagnosis of cardiovascular disease. Thus, the two applications are therefore claiming the same subject matter.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

H. Art of Interest

Jian *et al* (WO 98/07754) and Jian *et al* (WO 98/38311) disclose methods of treating and diagnosis of cardiovascular disorders using T1-R (Fit-1)-like molecules T1/ST2-receptor ligand II (WO 98/07754) and T1/ST2-receptor ligand III (WO 98/38311). These references are not being used as a basis for a 35 USC § 102 rejection; the Examiner merely notes that this is the closest prior art available.

I. Conclusion

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached on 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be

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reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BDH
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ROBERT S. LANDSMAN, PH.D.
PRIMARY EXAMINER